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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,679	05/12/2005	Johannes Pohlner	37998-237381	7233
26694	7590	06/02/2008		
VENABLE LLP P.O. BOX 34385 WASHINGTON, DC 20043-9998			EXAMINER MACFARLANE, STACEY NEE	
			ART UNIT 1649	PAPER NUMBER
			MAIL DATE 06/02/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,679

Applicant(s)

POHLNER ET AL.

Examiner

STACEY MACFARLANE

Art Unit

1649

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-8, 11, 14, 15 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-8, 11, 14, 15 and 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Claims 6, 7, 8, 11 and 21 have been amended, claims 1-5, 9-10, 12-13, 16-19 and 23-24 have been cancelled, as requested in the amendment filed on February 14, 2008. Following the amendment, claims 6-8, 11, 14-15 and 20-22 are pending in the instant application.

Claims 6-8, 11, 14-15 and 20-22, in so far as they read upon the elected species of rab31, are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3. Applicant's arguments filed on February 14, 2008 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112, second paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 6-8, 14-15, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 6 stands rejected for reasons of record in the Paper filed September 14, 2007. On page 10 of Remarks filed February 14, 2008, Applicant traverses the rejection on the grounds that the amendment to the claim obviates the relationship

between the cell being contacted and the rab31 being measured. Examiner disagrees. The amendment does not render clear that the cell even expresses "a translation product of a gene coding for rab31" as the claim reads upon "contacting a cell" (emphasis added), and that encompasses cells that do not express rab31.

7. Claim 7 stands as being rejected for the indefinite recitation of a "test animal which is predisposed to developing ...a neurodegenerative disease or related diseases or disorders" and "a matched control animal which is predisposed to developing ... a neurodegenerative disease or related diseases or disorders". On page 11 of Remarks filed February 14, 2008, Applicants traverse the rejection on the grounds that the specification describes that an animal can exhibit "a predisposition to developing symptoms of neuropathology similar to a neurodegenerative disease, in particular AD" as a result of, for example, "a modification of [an] endogenous gene, wherein said gene is mis-expressed, or under-expressed, or over-expressed." Examiner asserts that even determination by altered gene expression requires essential active steps that are omitted from the claimed method. One of ordinary skill in the art could not determine the metes and bounds of an animal that is predisposed. Moreover, because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a "predisposition", an artisan cannot determine if a animal which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation.
8. Claims 8, 14-15, and 20 are indefinite for depending from indefinite claims.

Claim Rejections - 35 USC § 112, first paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 6-8, 11, 14-15 and 20-22 stand as rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for reasons of record in the Paper filed September 14, 2007.

On page 12 of Remarks filed February 14, 2008, Applicant traverses the rejection on the grounds that the specification states a definitive physiological activity for "rab31, as a vesicle membrane-associated protein, participates in the regulation of vesicle trafficking, targeting and fusion." Applicant state that the specification further recites, "[r]ab31 may, for instance, impact on sorting and targeting of transport vesicles containing the amyloid precursor protein (APP) and, thereby, have a causative role in the development of AD." Applicant argues that by disclosing an activity of rab31, and noting altered expression in AD post-mortem samples versus controls, the specification fully enables the claims. While this has been considered in full it is not found persuasive to overcome the rejection for the following reasons.

One of ordinary skill in the art would easily recognize that the expression levels of many transcripts or proteins are measurably altered in a disease or pathological state. Since the disclosure has not provided evidence of a nexus between rab31 activity and neurodegenerative diseases then there is no reasonable evidence that one of ordinary skill in the art could perform the method as claimed and successfully screen

for a modulator of neurodegenerative diseases. The disclosure has failed to identify even one compound screened by the method that is useful as a modulator of disease. The guidance within the specification is merely prophetic regarding compounds identified by the method and how they may serve as a modulator of neurodegenerative diseases or related disorders. Thus, Applicant has not provided guidance that said method could be performed with a reasonable expectation of success.

Much remains with respect to the unpredictability of screening for modulators of neuron degenerative diseases and no definitive links between altered gene expression in neurodegenerative disease, such as familial inherited Alzheimer's disease, have lead to the discovery of modulators of these genes of interest that are valid treatments or biomarkers for AD. To date, no disease modulators have been identified from correlative neurodegenerative gene markers.

Furthermore, the claimed method encompasses the use of a transgenic animal and the instant specification has provided no guidance to one of ordinary skill in the art as to how to make and/or use the transgenic animal of the claims. The development of a transgenic animal is not trivial and much unpredictability remains within the art with respect to heterologous expression of genes.

Thus, Examiner maintains that the mere correlative evidence provided in the disclosure is an invitation for further experimentation and that one of ordinary skill in the art would have to perform undue experimentation in order to use the invention as claimed.

Conclusion

11. No Claim is allowed.
12. Any new grounds of rejection presented in this Office action were necessitated by Applicant's amendment. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M,W and ALT F 7 am to 3:30, T & R 5:30 -5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1649

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

/Olga N. Chernyshev, Ph.D./
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